

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Paul S. Keim et al.

Serial No.: tba

Filed: December 21, 2004

For: *A HIGH RESOLUTION TYPING SYSTEM FOR  
PATHOGENIC BORRELIA*

Art Unit: tba

Examiner: Unassigned

**INFORMATION DISCLOSURE STATEMENT**  
**PURSUANT TO 37 C.F.R. § 1.97**Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

Dear Sir:

Applicant hereby brings to the attention of the Examiner the documents noted on the accompanying Form PTO-1449. This Information Disclosure Statement is being filed before the mailing date of a first Office Action.

It is respectfully requested that the information cited herein be expressly considered during the prosecution of this application and made of record on any patent to issue therefrom. Inclusion of a reference on the enclosed 1449 is not to be construed as indicating the reference is prior art. Provision of this Information Disclosure Statement is not to be taken as evidence that a search has been conducted.

The Commissioner is hereby authorized to charge any cost that may be due to Deposit Account No. 17-0055.

Respectfully submitted,  
**QUARLES & BRADY STREICH LANG, LLP**December 21, 2004By: Barbara J. Luther  
Barbara J. Luther, 33,954

Attorney Docket No. 112624.00082

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| Sheet | 1 | of | 5 |
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| Application Number     |              |
| Filing Date            |              |
| First Named Inventor   | Paul S. Keim |
| Art Unit               | tba          |
| Examiner Name          | tba          |
| Attorney Docket Number | 112624.00082 |

## U. S. PATENT DOCUMENTS

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**FOREIGN PATENT DOCUMENTS**

| FOREIGN PATENT DOCUMENTS |                       |   |                                |   |   |                |
|--------------------------|-----------------------|---|--------------------------------|---|---|----------------|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T <sup>6</sup> |
|                          |                       | Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) |                                |   |   |                |
|                          | E                     | WO98/58943 A1   | 12-30-98                       | Fraser et al.                                   |   |                |
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| First Named Inventor   | Paul S. Keim |
| Art Unit               | tba          |
| Examiner Name          | tba          |
| Attorney Docket Number | 112624.00082 |

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|--------------------|-----------------------|---|----------------|
|                    | F                     | ANDERSON, J. F. 1991. Epizootology of Lyme borreliosis. Scand. J. Infect. Dis. Suppl. 77:23-34.   |                |
|                    | G                     | BALMELLI, T., 1995. Association between different clinical manifestations of Lyme disease and different species of Borrelia burgdorferi sensu lato. Res. Microbiol. 146:329-340.  |                |
|                    | H                     | BARBOUR, A. G., 1993. The biological and social phenomenon of Lyme disease. Science 260:1610-1616.  |                |
|                    | I                     | BELFAIZA, D., 1993 Genomic fingerprinting of Borrelia burgdorferi sensu lato by pulsed-field gel electrophoresis. J. Clin. Microbiol. 31:2873-2877  |                |
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|                    | K                     | BUSCH, U., 1996. Three species of Borrelia burgdorferi sensu lato (B. burgdorferi sensu stricto, B. afzelii, and B. garinii) identified from cerebrospinal fluid isolates by pulsed-field gel electrophoresis and PCR. J. Clin. Microbiol. 34:1072-1078.        |                |
|                    | L                     | CASJENS S, 2000. A bacterial genome in flux: the twelve linear and nine circular extrachromosomal DNAs in an infectious isolate of the Lyme disease spirochete Borrelia burgdorferi. Mol Microbiol. 35:490-516.   |                |
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**First Named Inventor**

**Paul S. Keim**

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|                    | P                     | DYKHUIZEN D.E. et al., 2001. The implications of a low rate of horizontal transfer in <i>Borrelia</i> . Trends Microbiol. 9:344-50.   |                |
|                    | Q                     | DYKHUIZEN D. E.et al., 1993. <i>Borrelia burgdorferi</i> is clonal: implications for taxonomy and vaccine development. Proc. Natl. Acad. Sci. USA 90: 10163-10167.  |                |
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|                    | T                     | FORTEZ, M., D. et al., 1997 Phylogenetic analysis of <i>Borrelia burgdorferi sensu stricto</i> by arbitrarily primed PCR and pulsed-field gel electrophoresis Int. J. System. Bacteriol. 47:11-18   |                |
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|                    | X                     | HUBULEK, Z.,et al., 1997. Distribution of <i>Borrelia burgdorferi sensu lato</i> genomic groups in Europe, a review. Eur. J. Epidemiol. 13:951- 957.  |                |
|                    | Y                     | KAWABATA, H., et al., 1993. Genomic analysis of <i>Borrelia japonica</i> sp. nov. isolated from <i>Ixodes ovatus</i> in Japan. Microbiol. Immunol. 37:841-848.  |                |

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|   |      | First Named Inventor     | Paul S. Keim |
|   |      | Art Unit                 | tba          |
|   |      | Examiner Name            | tba          |
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|   | Z                     | KEIM P. et al., 2000. Multiple-locus variable-number tandem repeat analysis reveals genetic relationships within <i>Bacillus anthracis</i> . J Bacteriol May; 182:2928-36.   |                |
|   | AA                    | MARCONI, R. T., et al., 1995. Identification of novel insertion elements, restriction fragment length polymorphism patterns, and discontinuous 23S rRNA in Lyme disease spirochetes: phylogenetic analyses of rRNA genes and their intergenic spacers in                                     |                |
|   | AB                    | MARTI Ras., et al., 1997 <i>Borrelia burgdorferi sensu stricto</i> , a bacterial species "made in the USA"? Int. J. System. Bacteriol. 47: 1112-1117   |                |
|   | AC                    | MURRAY, P.R., et al., 1999. Manual of Clinical Microbiology. 7th edition. ASM Press, Washington D.C.   |                |
|   | AD                    | NADELMAN, R. B., et al., 1998. Lyme borreliosis. Lancet 352:557-565.   |                |
|   | AE                    | NICHOLLS, T. H., et al., 1996. Lyme disease spirochetes in ticks collected from birds in mid-western United States. J. Med. Entomol. 33:379-384.   |                |
|   | AF                    | OHLENBUSCH, A., et al., 1996. Etiology of the acrodermatitis chronica atrophicans lesion in Lyme disease. J. Infect. Dis. 174:421-423.   |                |
|   | AG                    | PETER, O., et al., 1997. Association of distinct species of <i>Borrelia burgdorferi sensu lato</i> with neuroborreliosis in Switzerland. Clin. Microbiol. Infect. 3:423-411.   |                |
|   | AH                    | PICKEN, R. N., et al., 1998. Identification of three species of <i>Borrelia burgdorferi sensu lato</i> ( <i>B. burgdorferi sensu stricto</i> , <i>B. garinii</i> , and <i>B. afzelii</i> ) among isolates from acrodermatitis chronica atrophicans lesions. J. Invest. Dermatol. 110:211-214 |                |
|   | AI                    | POSTIC D., et al., 1999 Common ancestry of <i>Borrelia burgdorferi sensu lato</i> strains from North America and Europe. J. Clin. Microbiol. 37:3010-3012  |                |

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|   | AJ                    | POSTIC, D., et al., 1998. Expanded Diversity among California Borrelia isolates and description of Borrelia bissetii sp. nov. (formerly Borrelia group DN127). J. Clin. Microbiol. 36:3497-3504.  |                |
|   | AK                    | SCHMID, G. P. 1985. The global distribution of Lyme disease. Rev. Infect. Dis. 7:41-50.   |                |
|   | AL                    | WANG, G., et al., 1999. Molecular typing of Borrelia burgdorferi sensu lato: taxonomic, epidemiological, and clinical Implications. Clin. Micr. Rev. 12:633-653.  |                |
|   | AM                    | WEIR, B.S. 1990. Genetic Data Analysis. Sinauer Associates, Inc. Sunderland, MA. USA.   |                |
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